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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)
	09/701,132	REEVES ET AL.
Office Action Summary	Examiner	Art Unit
	Carla Myers	1634
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet wit	h the correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING Description of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by stature Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 136(a). In no event, however, may a re will apply and will expire SIX (6) MONT te, cause the application to become ABA	ATION. ply be timely filed HS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).
Status		
 1) ⊠ Responsive to communication(s) filed on 5/3; 2a) ⊠ This action is FINAL. 2b) ☐ Thi 3) ☐ Since this application is in condition for allows closed in accordance with the practice under 	s action is non-final. ance except for formal matte	• •
Disposition of Claims		
4)	awn from consideration. 3 and 66-69 is/are rejected.	in the application.
Application Papers	•	
9) The specification is objected to by the Examin 10) The drawing(s) filed on is/are: a) accomposition and accomposition and accomposition accomposition and accomposition and accomposition accomposition and accomposition	cepted or b) objected to be drawing(s) be held in abeyand ction is required if the drawing(s	ce. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119	•	
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat* See the attached detailed Office action for a list	nts have been received. Its have been received in Appority documents have been reule (PCT Rule 17.2(a)).	oplication No received in this National Stage
Attachment(s)	∧ □ ((DTO 442)
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 7/20/05; 5/31/05. 		/Mail Date ormal Patent Application (PTO-152)

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DETAILED ACTION

1. This action is in response to the amendment filed May 31, 2005. Claims 32, 34, 35, 37-38, 40-42, 46-49, 56-61, 63, 66-69 are now pending. Applicant's amendments and arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Election/Restrictions

2. This application contains claims directed to subject matter non-elected with traverse in Paper No. April 8, 2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

It is noted that the claims have been examined only to the extent that the claims read on SEQ ID NO: 13 and methods and compositions that require SEQ ID NO: 13 in combination with either SEQ ID NO: 56 or SEQ ID NO: 57. For example, in claims that recite the additional subject matter of the sequences of fragments of SEQ ID NO: 2, these claims have been examined only to the extent that the claims read on those portions of SEQ ID NO: 2 that include the sequences of SEQ ID NO: 56.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 32, 34, 35, 37-38, 40-42, 46-49, 56-61, 63, 66-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids consisting of SEQ ID NO: 1-68 and primers consisting of 10 to 20 nucleotide fragments of SEQ ID NO: 1 to 68 or consisting of the sequence of the specific nucleotide positions of SEQ ID NO: 56 of nucleotides 79-861, 2011-2757, 5257-6471, 13156-13821, 2744-4135 and 858-2042 of SEQ ID NO: 56 and methods of detecting *E. coli* using said nucleic acids as probes and primers, does not reasonably provide enablement for any nucleic acid comprising SEQ ID NO: 13, 56 or 57 or comprising a part of SEQ ID NO: 13, 56 or 57. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn broadly to include nucleic acids comprising SEQ ID NO: 13, 56 or 57; nucleic acids comprising 10-20 nucleotides of a fragment of nucleotides 586-606 or 791-810 of SEQ ID NO: 13; and nucleic acids comprising a sequence from nucleotides 586-810 of SEQ ID NO: 13. Claim 34 is further drawn to a nucleic acid consisting essentially of SEQ ID NO: 13. The specification does not provide a definition for the phrase 'consisting essentially of" as it relates to a nucleic acid sequence and thereby this phrase has been interpreted to include nucleic acids containing SEQ ID NO: 13 and any additional flanking nucleotides. Claims 46, 47 and 58 appear to include nucleic acids comprising fragments of SEQ ID NO: 56. While claims 46, 47 and 58 recite nucleic acids consisting of subfragments of SEQ ID NO: 56 (e.g., 'WbdN (nucleotide position 79 to 861 of SEQ ID NO: 56)"), the claims which depend from

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claims 46, 47 and 58, namely claims 48 and 60, further define these nucleic acids of consisting of smaller subfragments of SEQ ID NO: 2. It is also unclear as to whether claim 32 intends to encompass nucleic acids comprising subfragments of SEQ ID NO: 13, since claim 61 which depends from claim 32 further defines the nucleic acids of SEQ ID NO: 13 as consisting of primers that consist of subfragments of SEQ ID NO: 2. In view of the 'comprising" and 'consisting essentially of' language and the ambiguity in the dependent claims, the claims encompass nucleic acids that include SEQ ID NO: 13, 56 or 57 and unspecified flanking nucleotides and nucleic acids containing an unspecified fragment of SEQ ID NO: 13, 56 or 57 of any length (1, 2, 3 etc nucleotides) flanked by nucleotides of undefined identity and length. The claimed nucleic acids and compositions containing the nucleic acids are not defined in terms of any functional activity.

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement." In the instant case, the specification has not taught a representative number of nucleic acids within

the claimed genus and has not provided sufficient guidance as to how to obtain additional nucleic acids without undue experimentation. The specification teaches isolated nucleic acids consisting of SEQ ID NO: 1-68, wherein the nucleic acids encode a flagellin protein from one of the E. coli strains of H1, 2, 4-7, 9-12, 14-16, 18-21, 23-2, 26-34, 38, 39, 41-43, 45, 46, 49, 51, 52 and 56. The specification teaches comparing the sequences of SEQ ID NO: 1-68 to one another in order to identify sequences that are specific for a given H serotype. However, the specification (page 2) also teaches that there are 4 loci in E. coli which encode for flagellin proteins, namely flk, fl1, flm, and fliC. The specification teaches that it is not clear as to which loci some of the presently claimed nucleic acids have been obtained from. It is stated that 'we have used the term 'flagellin gene" in many cases where previously one would have used 'fliC" to allow for the uncertainty as to the locus introduced by recent observations" (see page 13). The specification asserts that most E. coli strains express a single H antigen and thereby it is the nucleic acid molecule itself that is important and not the source of the nucleic acid. Regardless of the fact that most E. coli strains only express one flagellin gene, it appears that all E. coli strains contain each of the 4 flagellin loci. Yet, the specification has taught a single nucleic acid from each of the stated H types. The claims encompass nucleic acids from each of the loci of flk, fl1, flm and fliC from the 54 known H types of E. coli. While it is unclear as to which loci have been taught by the specification, it is clear that the specification has not taught a representative number of nucleic acids from each of the loci in each of the possible serotypes of E. coli. Furthermore, the specification demonstrates the unpredictability in obtaining the full length sequence of

each of the flagellin genes in different E. coli H types. For example, at page 23, the specification states: '(f)or other strains, we were only able to amplify the flagellin gene using one or more of the other three pairs of primers, which are based on sequences within the fliC gene, and thus only partial sequence was obtained. These amplicons may be of the fliC gene or one of the alternative genes." At pages 26-28, the specification states that the full length flagellin genes from type strains H2, H3, H4, H5, H11, H17, H21, H24, H27, H29, H33, H38, H39, H42, and H56 have not been obtained. It is noted that the specification (page 24) states that the terminal regions of the flagellin gene are not important in determining antigenicity. However, the claims are inclusive of full length flagellin gene sequences which are not taught in the specification and the specification has established the unpredictability in obtaining these full length sequences. The specification (page 3) also teaches that the flagellin gene sequences for H8 and H40 were identical. Accordingly, these sequences cannot be used to determine the specific H serotype of E. coli but can only be used to determine whether the E. coli is type H8 or H40. Further, the specification (page 40) states that '(o)ur work has shown that there are at least 7 cases where the H antigen type strains carry two antigen genes which appear to be complete and have the potential to function." The specification does not provide sufficient guidance as to how to obtain the flagellin genes from each of the 4 loci without undue experimentation. Further, the specification does not provide sufficient guidance as to how to distinguish between the nucleic acids from these loci and how to predictably identify subsequences within these as yet unisolated loci which are specific for an H serotype. As discussed by the specification the art of

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identifying and isolating the different flagellin genes from different loci is unpredictable. It is further unpredictable as to which sequences within these loci will be specific for a given H serotype. As taught in the specification (for example, page 31), some cross-reactivity with different strains is observed depending on the level of dilution of the antisera. For example, H11 cross reacts with anti-H21 and anti-H40. Accordingly, selection of subfragments of the flagellin gene that encode for type H specific antigens is unpredictable and can only be determined through experimentation. The claims also include SEQ ID NO: 9 which is characterized as being specific for H7 and SEQ ID NO: 14 which is specific for H12. It is unpredictable as to how these sequences which are specific for H1, H7 and H12 can also not encode a protein expressed by E. coli H1, H7 or H12. Additionally, the claims include nucleic acids which include only a portion of SEQ ID NO: 13, 56 and 57.

The claims do not define the identity of the surrounding nucleotides and do not state the particular fragments which would be required to provide the requisite attribute of allowing for the specific H serotype. For example, the specification does not teach how to use a nucleic acid that includes 1, 10, or 20 nucleotides, etc. of SEQ ID NO: 13 flanked by nucleotides of any length and identity as a probe or primer. The claims thus include a very large genus of nucleic acids which are not adequately disclosed in the specification. Adequate guidance has not been provided in the specification as to how to predictably identify additional nucleic acids useful for determining the O serotype of E. coli without undue experimentation. Additionally, the steps recited in the method claims do not further define the structural or functional properties of the nucleic acids

because the claims include detecting nucleic acids that hybridize to any degree and with any specificity to the claimed nucleic acid molecules under any conditions in order to detect any nucleic acid molecule that forms a hybrid with the claimed nucleic acids as a means 'to detect the H and O serotype of the E. coli in the sample." Accordingly, in view of the lack of information in the specification as to how to reasonably identify other flagellin genes and genes useful for determining the O serotype of E. coli without undue experimentation and in view of the unpredictability in the art, the specification has not adequately taught one of skill in the art how to practice the claimed invention as it is broadly claimed.

Response to Arguments:

In the response, Applicants traverse this rejection by stating that the specification teaches that nucleotides from SEQ ID NO: 13 flank the claimed fragments of SEQ ID NO: 13. It is stated that '(t)he sequence from position 586 to position 810 is in a central portion of SEQ ID NO: 13, and the sequence from 586 to 810 is therefore flanked by additional nucleotides in SEQ ID NO: 13."

This argument has been fully considered but is not persuasive because the claims are not limited to fragments that are flanked by the specific sequences of SEQ ID NO: 13. Rather, the claims encompass fragments that are flanked by nucleotides of any identity and number. Further, no functional activity has been recited for the nucleic acids comprising such fragments. If Applicant's intend to claim fragments that are flanked by only the sequences of SEQ ID NO: 13, then the claims should be amended to recite, for example, 'An isolated nucleic acid consisting of 20 or more nucleotides of SEQ ID NO:

13" or 'An isolated nucleic acid consisting of a fragment of SEQ ID NO: 13, wherein said fragment comprises nucleotides 586 to 810 of SEQ ID NO: 13."

The response further states that the specification teaches that the flagellin H11 gene may be cloned into a plasmid containing additional sequences. This argument has also been fully considered but is not persuasive because the claims are not limited to nucleic acids in which the sequences of SEQ ID NO: 13 are flanked by heterologous plasmid sequences.

Lastly, the response asserts that 'no evidence has been presented that shows that a skilled worker could not make and use a claimed nucleic acid. It is agreed that a few sequences have been disclosed that include nucleotides in addition to those from a recited region of SEQ ID NO: 13. However, it must be remembered that this application was first filed in 2000, long after the wave of genetic engineering brought in by Cohen and Boyer and others."

This argument has also been fully considered but is not persuasive. As set forth in the above rejection, the teachings in the specification provide the evidence that, at the time the invention was made, the generation and use of nucleic acids comprising fragments of SEQ ID NO: 13 was unpredictable and not fully enabled. At pages 26-28, the specification states that the full length flagellin genes from type strains H2, H3, H4, H5, H11, H17, H21, H24, H27, H29, H33, H38, H39, H42, and H56 have not been obtained. The specification discusses the difficulty in obtaining the full length flagellin genes. There is no specific guidance provided in the specification as to how one could overcome the noted problems in order to allow for the isolation of the full length H11

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flagellin gene without undue experimentation. Further, the specification teaches that the fragments of SEQ ID NO: 13 are to be used to distinguish between the different strains. However, the specification does not provide sufficient guidance as to how to predictably identify subsequences within these as yet unisolated loci which are specific for an H serotype. The specification (page 31) also points out the problems with cross-reactivity between the different strains. Yet, the specification does not teach a predictable means for determining the number and identity of nucleotides which could be added to subfragments of the flagellin gene, so as to generate nucleic acids which code for H specific antigens or which are useful for detecting E. coli strains. Accordingly, the teachings in the specification provide the evidence of the unpredictability of obtaining full length sequences encoding for the H11 flagellin gene and the unpredictability in selecting fragments of the H11 flagellin gene and flanking nucleotides which could be used for the purposes set forth in the specification of encoding for antigenic peptides or as primers or probes for detecting E. coli strains.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS TO THE CLAIMS:

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 59, 60, 61 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 48 is indefinite and unclear. The claim refers to the nucleic acids of step (a) of claim 46 or 47, wherein the referenced nucleic acids consist of distinct fragments of SEQ ID NO: 56 (e.g., nucleotides 79-861 of SEQ ID NO: 56). Yet, the claim then further defines the nucleic acids as consisting of a smaller fragment of SEQ ID NO: 2 (e.g., nucleotides 79-92 of SEQ ID NO: 2). Accordingly, it is unclear as to what is intended to be the relationship between the 'nucleic acid molecule of step (a)" and the forward or reverse primer. Similarly, claims 60 and 61 are indefinite because it is not clear as to what is intended to be the relationship between the larger nucleic acid of step (b) and (a) consisting of fragments of SEQ ID NO: 56, respectively, and the smaller

Claim 48 is also indefinite because the claim does not recite a closed Markush group since the claim does not end in a period.

forward and reverse primers consisting of fragments of SEQ ID NO: 2.

Claim 59 is indefinite and confusing over the recitation of 'a nucleic acid molecule according to claim 32 SEQ ID NO: 57" because it is unclear as to whether the nucleic acid molecule consists of or comprises the nucleic acid of claim 32 or consists of or comprises the nucleic acid molecule of SEQ ID NO: 57.

Claim 61 is indefinite over the recitation of 'the nucleic acid of step (a) comprises a forward and a reverse primer." The claim refers to a single nucleic acid molecule (i.e., an isolated and purified nucleic acid molecule comprising SEQ ID NO: 13), but then further limits this molecule to one that comprises 2 separate forward and reverse primers. Accordingly, it is unclear as to what is intended to be the relationship between the single nucleic acid molecule 'of step a" and the forward and reverse primes.

Claim 67 is indefinite and confusing over the recitation of 'one or more nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 57." It is unclear as to whether the claim intends to refer to an additional undefined sequence or to 2 or more nucleic acids, each comprising SEQ ID NO: 57 or to a nucleic acid comprising multiple copies of SEQ ID NO: 57.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirzabekov (U.S. Patent No. 6,090,549).

Mirzabekov (paragraph 99) discloses hybridization chips containing all possible 8-mers. It is noted that the present claims are inclusive of primers and compositions comprising primers wherein the primers comprise "about 10" nucleotides of position 586-606 or 791-810 of SEQ ID NO: 13. The specification and claims do not further define what is intended to be encompassed by "about 10" and thereby this phrase has been interpreted to include primers of 8 nucleotides. Further, the claims do not require that the primers are isolated or purified from other primers. The claims are thereby inclusive of arrays containing all possible 8 mers. The array of Mirzabekov containing all

possible 8 mers would necessarily include 8 nucleotides from a fragment of SEQ ID NO: 13 including nucleotides 586-606 or 791-810. Additionally, the 8-mers of Mirzabekov are considered to be primers because these 8-mers may be extended at the 3' end. Accordingly, the claimed invention is anticipated by Mirzabekov.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov in view of Ahren (The Scientist. July 1995. 19 (155): 20-24).

The teachings of Mirzabekov are presented above. Mirzabekov does not teach packaging the arrays comprising 8-mers in kits.

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However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, Ahren discloses the general concept of kits for performing nucleic acid detection methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay and allows investigators to save time and money (see for example page 23). Accordingly, it would have been prima_facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the arrays comprising 8-mers in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to use the arrays for the detection or sequencing of target nucleic acids.

It is noted that the recitation of "for identifying the H serotype of E. coli" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims. As stated in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999), if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers September 19, 2005

CARLA J. MYERS
PRIMARY EXAMINER